

Art Unit: 1654

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Art Crawford, Applicant's Representative, on 7/8/09.

### **IN THE CLAIMS**

In claim 73, lines 3-4, the phrase "as defined in claim 59" has been deleted, and the phrase --comprising an aromatic alcohol absorption enhancer chosen from propyl gallate, butylated hydroxy toluene (BHT), butylated hydroxy anisole (BHA) and analogues and derivatives thereof, wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principle, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7, and wherein when the aromatic alcohol is propyl gallate or an analogue or derivative thereof, the composition further comprises a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media-- inserted therein.

Claims 59-72, 83-87, and 90-91 have been cancelled without prejudice.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: the present methods of use (independent claims 73 and 75) were not found to reasonably teach or suggest a method of enhancing the absorption of an active macromolecule principle (e.g. peptide) which comprises an aromatic absorption enhancer chosen from propyl gallate, butylated hydroxyl toluene (BI4T), butylated hydroxyl anisole (BI4A) or analogues/derivatives thereof, because:

1) 1<sup>st</sup>, there is no teaching/suggestion/motivation in the references of record, and thus it would not have been obvious to use these antioxidants to enhance absorption of active macromolecule principles, since they are not water-soluble, and are therefore not predictable for one of ordinary skill in the art to use them for the stated purpose of absorption enhancement of the active macromolecular principle (as to both independent claims 73 and 75) ; and

2) 2<sup>nd</sup> and further (as to narrower claimed independent claim 73), there is no teaching/suggestion/motivation in the references of record, and thus it would not have been predictable and thus obvious for one of ordinary skill in the art to have employed such antioxidants to enhance absorption in an amount by weight greater than or equal to that of the active macromolecular principle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Conclusion***

Claims 73-82, 88-89, and 92-93 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960.

The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/8/2009

/Maury Audet/  
Examiner, Art Unit 1654  
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